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510(k) SUMMARY
BAGTech's BioAquaCare™

Submitter's Name, Address, Telephone Number, Contact Person and Date Prepared

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DEC 2 1 2007

Contact Person: Jonathan S. Kahan, Partner

Date Prepared: July 26, 2007

Name of Device and Name/Address of Sponsor

Name of Device : BioAquaCare™

Sponsor : BioArtificial Gel Technologies (BAGTech) Inc
400 de Maisonneuve West, Suite 1156
Montreal (Quebec)
H3A 1L4 Canada

Common or Usual Name Hydrogel Wound Dressing

Classification Name Dressing, wound, drug

Classification: Unclassified

Product Code: FRO

Predicate Devices

Xylos Corporation's XCell® Antimicrobial Wound Dressing

AcryMed Inc.'s AcryDerm Gel Wound Dressing

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Intended Use / Indications for Use

BioAquaCare™ is an hydrogel wound dressing intended for the management of wounds and provides a moist environment that supports the autolytic debridement of areas of the wound that are necrotic. BioAquaCare™ wound dressing provides an effective barrier to resist microbial colonization within the dressing and reduce microbial penetration through the dressing. It is intended for use with dry, light and moderately exuding partial and full-thickness wounds such as minor burns, superficial injuries, lacerations, cuts, abrasions, incisions and surgical wounds, and skin tears. The dressing also protects against abrasion, desiccation, and external contamination. The moist environment has a cooling effect that may reduce pain.

Under the direction of a health care professional, BioAquaCare™ is indicated for the local management of: (1) chronic wounds such as pressure ulcers, lower extremity ulcers, venous ulcers, arterial ulcers, and, diabetic ulcers; and (2) 2nd degree burns and donor sites.
BioAquaCare™ is intended for single use only.

BioAquaCare™ is not intended for treatment of third degree burns.

Technological Characteristics

BioAquaCare™ wound dressing is composed of the following ingredients: 1) PEG-Soy protein; 2) EDTA; 3) sodium phosphate; 4) sodium chloride; 5) water; and 6) Liquid Germall Plus® as a preservative. The preservative contained in BioAquaCare™ aids in providing an effective barrier to resist microbial colonization within the dressing and reduce microbial penetration through the dressing. BioAquaCare™ contains up to 95% water which enables the dressing to provide a moist environment even if the wound bed is dry. BioAquaCare™ will not breakdown during use, so all the BioAquaCare™ components are removed from the wound when the dressings are lifted away. BioAquaCare™ does not include any medicinal substance, animal/human tissue or biologics. BioAquaCare™ is supplied either with or without medical grade gauze for mechanical support, and with a backing which serves to control the rate of water evaporation from the wound dressing upon application to the wounds.

BioAquaCare™ is packaged in either a single use blister packages or in plastic bag. BioAquaCare™ is supplied in a variety of sizes (i.e., 5 cm x 5 cm, 10 cm x 10 cm, 8 cm x 20 cm, 10 cm x 20 cm, or 10 cm x 27 cm). BioAquaCare™ is manufactured under aseptic conditions in a controlled class 100 clean room environment.

Performance Data

Various in vitro and animal studies were conducted to characterize BioAquaCare's biocompatibility, preservative system's effectiveness and, effectiveness in the management of different types of wounds including partial thickness wounds , full thickness wounds, incision wounds, thermal burns, chemical burns and scarification.

In all instances, BioAquaCare™ functioned as intended and the performance observed was as expected.

Substantial Equivalence

BioAquaCare™ is as safe and effective as the predicate devices. BioAquaCare™ has the same intended uses and similar indications, technological characteristics, and principles of operation as its predicate devices. The minor technological differences between BioAquaCare™ and its predicate devices raise no new issues of safety or effectiveness. Thus, BioAquaCare™ is substantially equivalent.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 2 1 2007

BioArtificial Gel Technology
% Hogan & Hartson, LLP
Mr. Johnathan S. Kahan
Columbia Square
555 Thirteenth Street, Northwest
Washington, District of Columbia 20004

Re: K072068
Trade/Device Name: BioAquaCare™
Regulatory Class: Unclassified
Product Code: FRO
Dated: December 13, 2007
Received: December 13, 2007

Dear Mr. Kahan:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

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Indications for Use Statement

510(k) Number (if known): K072068

Device Name: BioAquaCare™

Indications for Use:

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Prescription Use __X__ AND/OR Over-The-Counter Use ____
(Part 21 C.F.R. 801 Subpart D) (21 C.F.R. 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE -- CONTINUE ON ANOTHER PAGE IF NEEDED)

_____ Concurrence of CDRH, Office of Device Evaluation (ODE)

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(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K072068